REMARKS

Claims 149-192 are pending in the application. No claims are allowed.

Claims 149-192 have been canceled and are replaced by newly presented claims 193-238.

It is believed that all amendments are fully supported in the specification and are believed not to add new matter. It is believed that all amendments are fully supported in the specification and are believed not to add new matter. The following table identifies specific paragraphs, figures or original claims in the specification of U.S. Pat. App. **20040116379** to facilitate finding support for various indicated claim limitations.

Claim number and Claim Limitation	Paragraph Number in Published App. Nr. 20040116379
Glucan MW Independent cl. 193, 219 Dependent cl. 208-210, 233-235	[0016];[0109] and Figure 9.
Antigens, cancers Independent cl. 193, 219 Dependent cl. 197-207, 223-227	[007; [0049]; [0259]; Original claim 22, among others throughout spec.
Glucan viscosity Independent cl. 193, 219 Dependent cl. 216-218, 236-238	[0101]; [0109]
Glucan side chains; Mixed linkages Dependent cl. 213-215;229-231	[004]; Original claim 46

Per a telephone conversation with Examiner Olson on January 31, 2007 additional amendments removed and clarified certain claim limitations. For example, claim limitations referring to "synergistic" effects or "synergism" have been deleted. Further, the approximate lower molecular weight limits of functional β-glucans was included in the independent claims.

Applicants gratefully acknowledge the time and attention of Examiner Olson and Supervisor Jiang in participating in a telephone interview on January 22, 2007.

REJECTIONS UNDER § 112, 1ST PARAGRAPH

Applicant respectfully disagrees with Examiner as to the propriety of this rejection for reasons already of record. However, in order to expedite the allowance of this application, Applicant has amended the claims in accordance with the scope of the subject matter that Examiner specifies as enabled. Thus, independent claims 149, 168 and 189 recite the specific cancer cell types for which Applicant has actually exemplified the β-glucan-mediated enhancement of anti-tumor antibodies.

Claims 149-192 are rejected for allegedly not being supported by an enabling disclosure. The Office Action asserts that the specification "while being enabling for a beta-glucan and one or more specific monoclonal antibodies for the treatment of specific cancers, does not reasonably provide enablement for methods and compositions comprising any antibody whatsoever for the treatment of any cancer whatsoever." Office Action, p. 3.

It is respectfully submitted that these amendments overcome the rejection under § 112, 1st paragraph and should be withdrawn.

DOUBLE PATENTING

Statutory Type

The provisional rejection of claims 149-167 over claims 89-107 of application USSN 11/218,044 under § 101 is acknowledged. Should Examiner find the amendments and remarks filed herewith sufficient to remove all other rejections in the instant application, Applicants will promptly cancel claims 89-107 of the '044 application, or corresponding replacement claims, or amend them so as to be patentably distinct.

Nonstatutory Type

The provisional rejection, on the ground of nonstatutory double patenting, of claims 168-192 over claims 89-107 of application USSN 11/218,044 under § 101 is acknowledged. Should Examiner find the amendments and remarks filed herewith sufficient to remove all other rejections in the instant application, Applicants will promptly cancel claims 89-107 of the '044 application, or corresponding replacement claims, or amend them so as to be patentably distinct.

REJECTION UNDER 35 USC § 103(a)

Preliminary Comments

Claims 149-154, 156-176, and 180-192 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. (Reference 55 cited in PTO-1449) in view of Jamas et al. (US patent 5859720). Yan does not teach or suggest oral administration of a glucan, however the

Office Action asserts that Jamas et al. discloses an orally administered immune-stimulating beta-glucan preparation, derived from yeast, bacteria, fungi, and plants. (Column 4, lines 40-64).

The Office Action then concludes;

> One of ordinary skill in the art would have reasonably expected success in producing an appropriate pharmaceutical composition and administering the claimed dose because the preparation of pharmaceutical composition comprising known active ingredients and the selection of specific dosages of known medications is part of the ordinary and routine level of skill in the art. One of ordinary skill in the art would reasonably have expected success in using the composition of Jamas et al. because this composition comprises a beta-glucan which has the same backbone and linkages as that used by Yan et al. Thus the invention taken as a whole is prima facie obvious.

The crux of Examiner's rationale appears to be that Jamas's mere reference to orally administered glucan constitutes sufficient "teaching" to provide a reasonable expectation of success in arriving that the claimed subject matter.

Applicant respectfully, disagrees. It is respectfully suggested that persons of ordinary skill in the art would not, nor could not, have had a reasonable expectation of success in performing the Applicant's method by modifying the teachings of Yan with Jamas's unsubstantiated and nonenabled suggestion that orally administered glucan would have been effective in his experimental system.

Response to Examiner's Statements

In describing Jamas's β-glucan composition Examiner states:

This beta-glucan has a 1,3-linked backbone and 1,6-linked branches, (column 4, lines 11-20) and is **thus the same glucan described by Yan et at.** The necessary dose varies on an individual basis. (column 4, lines 49-53); and

Response:
Examiner incorrectly assumes that Jamas used the same β-glucan as Yan. This is not the case. Yan's glucan has a molecular weight of about 10,000 Da (Yan, p.3046, col. I,last ¶) while Jamas's has an average molecular weight of about 225,000 Da. (Col. 7/lines 5-7). In other words Jamas β-glucan is > 20 times larger than Yan's. It is indisputable that the two could not have used the same β-glucan. Therefore, Examiner's belief that all that persons of ordinary skill in the art needed to arrive at the claims was dosing data is entirely unsupported by the references and, is inorrect.

In describing Jamas's β-glucan composition Examiner states:

Jamas et al. discloses an orally available, immune-stimulating beta-glucan preparation, (column 4, lines 40-64) derived from yeast, bacteria, fungi, and plants. (column 1, lines 13-15)…

Response:
The term "orally available" is entirely non-descriptive and is used merely to obfuscate the fact that Jamas does not describe or enable oral administration of anything. This statement has absolutely no probative value. In fact the term "orally available" evidences the use of hindsight in an attempt to create a rejection where there is not one. The actual cited passage does not use or allude to the term "oral."

In describing why persons of ordinary skill in the art would have looked to Jamas for guidance in modifying Yan, Examiner states:

One of ordinary skill in the art would have been motivated to use the composition of Jamas et al. because this composition contains a beta-glucan having the same 1,3 and 1,6-linkages described by Yan et al.
Response:
As shown above, Yan and Jamas do not use the same or even similar β-glucans. Simply having both 1,3-β and 1-6-β linkages indicates little when Jamas's β-glucan is >20 times the size of Yan's. Jamas further states, "[t]he biological activity of PGG glucan can be controlled by varying the average molecular weight and the ratio of 1,6-β to 1,3-β linkages…" Col. 4/lines 18-22.

Therefore, the rationale of the rejection being based on the similarity of the β-glucans used by Yan and Jamas is not supported by the art of record or other data. Accordingly this rejection should be withdrawn.

In describing why persons of ordinary skill in the art would have looked to Jamas to modify Yan, Examiner states:

One of ordinary skill in the art would have been motivated to formulate the beta-glucan separately for oral administration because the composition of Jamas et al. is capable of producing a systemic effect when administered orally.

Response:

Examiner has not provided a single piece of evidence that Jamas's "systemic effect" is in any way related to what either Yan or Applicant has disclosed. The only "systemic" experiment was that described in Example 5, col. 8. He simply showed an increase in different types of white blood cells. Fig. 2 and 3.
Similarly, Figure 4 shows that PPG seemed to protect against *E. coli* sepsis. The relevance of this data to the claimed subject matter and Yan's results need explanation in order for the rejection to scientifically sound. This has not yet been provided.

Yan's disclosure relates to the use of antibodies in suppressing tumor growth in vivo. Jamas shows no tumor cell data of any type, let alone in vivo. Jamas does not employ any immunoglobulin. The word "immunoglobulin" does not appear in the Jamas reference at all. It is respectfully requested that Examiner extrapolate the teaching of Jamas to that of Yan in a scientifically coherent manner so that we can clearly understand his rationale as to why persons of ordinary skill in the art would have combined the two references, with a reasonable expectation of success.

In conclusion, many critical statements and conclusions in the office action do not provide an accurate account of the references' teachings, let alone reflect the state of the art at the time of filing. The subject office action is devoid of a cohesive view of how the combined references could provide a reasonable expectation of success, especially in view of the unpredictability in the art. It is difficult to understand how this combination of references can be seen as sufficient as a *prima facie* case of obviousness, or overcome the presumption that newly filed claims are patentable.

1. The Claimed Subject Matter

The claims encompass a pharmaceutical combination of therapeutic agents for suppressing tumor growth and/or volume. The major inventive aspect of the invention is combining an orally formulated and administerd β-glucan with administered tumor/cancer-specific antibodies. There is not a single piece of prior art suggesting or disclosing such a method. This is supported by the fact that at the time of Applicant's earliest priority date, January 16, 2001, the magnitude of the enhancement of antibody-related tumor suppression by the orally administered glucan was very surprising and unexpected in view of the lack of understanding and predictability of the oral delivery and bioavailability of macromolecules. (Discussed below in detail).

In addition, it was further unexpected that the enhancement of antibody-related tumor suppression by the orally administered β-glucan could be demonstrated with several distinct types of antibodies that recognize distinct antigens on distinct tumor cell types.

It is respectfully emphasized that the patentability of the claimed combination and its method of use is based largely on the fact that the effect was achieved with the orally administered β-glucan. Although persons of ordinary skill in the art would appreciate the general desirability of a noninvasive route of administration of β-glucans, this had not resulted in any therapy regimens based on oral delivery of the β-glucans. This is why at the time of Applicant's priority date, oral administration of β-glucans had not achieved any recognized status in the fields of chemotherapy or immunology as a means to suppress malignant tumors or bacterial

infections. Accordingly there were also no prior reports by others in the art that attempted or suggested the claimed subject matter.

2. Brief Chronology of the Literature on the Oral Administration of Glucans in Treating Tumors

The anti-tumor activity of a partially purified β-glucan was first reported by Ohno, et al., in 1986. See Exhibit A. Ohno explored the anti-tumor effects in mice of 1,3-β glucan administered either intraperitoneal (i.p.), intravenous (i.v.), intratumoral (i.t.) or orally (p.o.). Ohno concluded that tumor growth was significantly inhibited by the glucan when administered i.p., i.v., or i.t. "However, oral administration was not effective." Exhibit A.

The same laboratory published another study showing that a different fungal 1,3-β glucan showed significant tumor inhibition when orally administered directly after tumor implantation. Thus, under conditions where the tumor was not given a period of growth prior to challenge with β-glucan, some inhibition was seen. They concluded that the oral 1,3-β glucan could function as an immunomodulator. Exhibit B. However, as late as 1995, it was also reported that dietary β-glucan increased the susceptibility of porcine to lethal bacterial challenges. Exhibit B.1. Thus, the effects of oral glucan have been spotty and contradictory. Very few studies even deal with tumor-suppression, but as in Jamas, are directed to combating bacterial infection.

Importantly, Examiner is respectfully reminded that these and other early experiments in immunomodulation by β-glucan did not involve administering an anti-tumor antibody. In fact, the issue was not even referred to in the abstracts and references reviewed. This is consistent with the Jamas reference showing only an effect on

macrophage behavior in vitro after i.p./i.v treatment. The word "antibody" does not even appear in Jamas. Thus, the state of the art did not recognize oral administration of 1,3-β glucan as equally dependable to i.v., i.p. or i.t. methods for experimental or therapeutic purposes. This is consistent with Applicant's results being highly unexpected, and therefore, nonobvious in view of the art.

3. Rejection Under § 103(a) Over Yan and Jamas is Inconsistent With Examiner's Rejection Under § 112, 1st,Para.

The Examiner's rationale in maintaining the previous § 112 rejection alleging lack of enablement for different cancers, was based on the silver bullet concept. Briefly, a given combination therapy for treating a cancerous tumor cannot be expected to be effective for other cancerous tumors. Examiner's conclusion that oral administration of 1,3-β glucan has a reasonable expectation of success in providing supra-additive enhancement of any administered anti-tumor antibody in treating any cancer runs completely counter to the silver bullet concept. It is respectfully submitted that Examiner cannot selectively and inconsistently apply lines of reasoning when evaluating claims under different statutory provisions.

Examiner is suggesting that Yan in view of Jamas provides a silver bullet for all of the cancers and antibodies exemplified in Applicant's specification. It is respectfully submitted that the Examiner cannot have it both ways. If Examiner applies his silver bullet notion consistently, he would be compelled to conclude that the rejection in view Yan/Jamas does not establish prima facie obviousness.

The following are a few of the major facts of record militating against a finding of obviousness. It is respectfully submitted that Examiner has not provided any evidence of record to contradict or seriously call into question the validity of even one of these facts:

a. There are no references or evidence on record to indicate that, oral administration can generally be expected to provide the effects of intravenous, intra-peritoneal, subcutaneous or direct intratumoral administration of a therapeutic agent.

b. With respect to β-glucans specifically, there are only few reports on orally administered β-glucans, and they do not involve effects on administered anti-tumor antibodies. Even in those cases orally administered glucans were most often without effect, whereas other routes of glucan administration were effective. Most studies focused on the in vitro behavior of macrophages in β-glucan-treated animals, with further focus on the role of induced cytokine levels.

c. Jamas is representative of the art at that time in that he studied the effects of β-glucans on bacterial infections. He examined the effects of intravenous and subcutaneous β-glucan on macrophages. The words antibody or immunoglobulin do not even appear in Jamas's specification. Further, Jamas did not demonstrate the effectiveness oral β-glucan administration but only provided a brief non-enabling reference to it.

d. It is indisputable that for decades, persons of ordinary skill in the art recognized the difficulties associated with therapeutics being absorbed from the gastrointestinal tract. The intestinal mucosa has historically been an art-recognized formidable barrier

to delivering therapeutic agents in either effective amounts and/or functionally intact.

It is respectfully submitted that this fact by itself defeats a conclusion that oral β-glucan administration provided a reasonable expectation of success in enhancing an administered antibody. Examiner's adherence to the unpredictability inherent in his "Silver Bullet" arguments must be applied consistently herein. It is respectfully submitted that doing so would compel the withdrawal of the rejection under § 103(a).

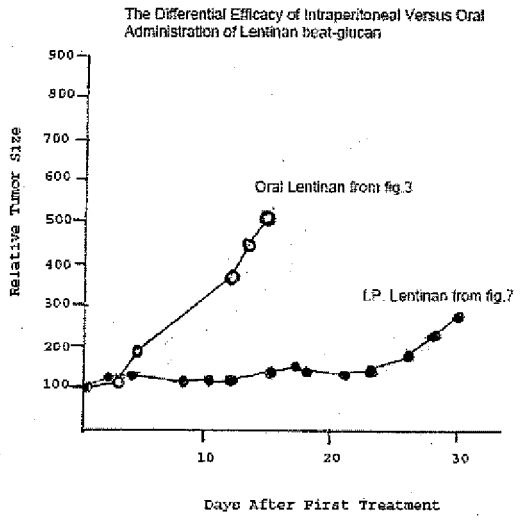
e. The literature on 1,3-β glucan, in its entirety, does not include even a single instance of combining orally administered glucan with any kind of antibody until Applicant's work was published. Thus, the alleged obviousness of the claimed subject matter is not supported by the knowledge in the art.

In view of these factual distinctions over the art, it is respectfully suggested that the rejection over Yan and Jamas does not stand up to proper application of § 103(a) or Examiner's silver bullet test.

4. Applicant Provides Direct Evidence That the Claimed Subject Matter is not Obvious

According to the instant rejection, Yan's disclosure of intraperitoneally ("i.p.") administered glucan together with Jamas's "suggestion", would render the claims obvious. This requires that these references, along with knowledge in the art provide persons of ordinary skill in the art a reasonable expectation of success. MPEP 2141(II). The graph shown below indicates that there could not be a reasonable expectation of success extracted from the prior art.

The figure below has been re-drawn from the corresponding data in Fig. 3 and Fig. 7 of the specification. The results compare the efficacy of administering 1,3-β glucan orally (open circles) versus i.p (closed circles). The data clearly establish that administering the β-glucan lentinan i.p. efficiently enhanced the antitumor suppressive effect of administered antibodies. In contrast, orally administered lentinan had little if any effect.



Thus, as of Applicant's earliest filing date, persons of ordinary skill in the art could not have had a reasonable expectation of success in modifying Yan with Jamas and arrive at the claimed subject matter. This dramatic demonstration exemplifies precisely the type of direct comparison that tests the 103(a) rejection's underlying assumptions, and proves that the rejection is not properly based on the art. Further, these results also establish that the rationale behind the rejection is not scientifically correct.

Accordingly, it is respectfully submitted that the rejection should be withdrawn.

5. Persons With Greater Than Ordinary Skill in the Art Recognized the Claimed Method as a Breakthrough

During the manuscript review process leading to the 2002 publication of Cheung, et al., the following comments were provided by anonymous Reviewer B:

> This manuscript reports a potentially important observation in the development of β-glucan adjuvant therapy. Previous studies primarily in Japan had focused on fungal-derived β(1,3)-glucans that were given intravenously without a clear understanding of mechanism and with unpredictable outcome. Following up on reports that β-glucans functioned through a priming of leukocyte CR3…, the author have not only confirmed the requirement for combination therapy with complement-activating monoclonal antibodies, but have made the important discovery that the β-glucan could be given orally rather than intravenously, and that cereal grain-derived β(1,4)-glucans could be effective adjuvants with [sic] given orally instead of the more costly and difficult to obtain fungal β(1,3)-glucans that are generally given intravenously.

See Exhibit C. (Emphasis added).

In brief, the passage above indicates that an expert in the field interpreted the prior art as unpredictable, and that the claimed method comprising oral delivery of β-glucan was an "important discovery." The text indicates that the reviewer was well aware of the kind of work that Jamas discloses and considered it unclear and unpredictable.

In conclusion, it is respectfully submitted that Examiner's belief that the oral administration of β-glucans was sufficiently known and predictable so as to render the claims obvious is simply not supported by expert opinion. Accordingly, the rejection is improper and should be withdrawn.

6. The Claimed Subject Matter Meets a Long-Felt Need and Breaks With Conventional Wisdom

Objective evidence or secondary considerations such as unexpected results, commercial success, long-felt need, failure of others, copying by others, licensing, and skepticism of experts are relevant to the issue of obviousness and must be considered in every case in which they are present. When evidence of any of these secondary considerations is submitted, the examiner must evaluate the evidence. MPEP 2141, III.

The oral delivery of peptides and proteins has long been dubbed the "HOLY GRAIL" of drug delivery. Exhibit D, p.1. The state of the art of oral delivery of therapeutic agents is described in Exhibit E, which is a review focusing on the critical issues relating to transmucosal transport of protein therapeutics from the gastrointestinal tract into the blood. The authors make the relevant point that macromolecules other than polypeptides also confront virtually identical barriers to gastrointestinal absorption. Exhibit E, p. 142, col. 2. The most relevant problems in oral delivery relate to the harsh environment of the stomach and the transport of the therapeutic agent across the mucosal layer of the small intestine. Exhbit E, p. 143, col. 1, 3rd para., to p. 144,col. 3.

The ongoing problems in oral delivery include poor bioavailability and unpredictability of a treatment's effectiveness. It is noted that as late as 2004, the date of Exhibit E's publication, these problems had not been effectively resolved.

Many of the chemotherapeutic agents given orally do not have as high a bioavailability...and methods to increase their absorption are under investigation. In fact, the bioavailability of most chemotherapeutics is very low and also variable when administered orally. These difficulties create higher cost as well as risk of an inappropriate dose due to unpredictable uptake. Some of the mechanisms leading to these problems and potential solutions will be discussed here. See Exhibit E, p. 148, col. 2, 2nd para.

Thus, persons of ordinary skill in the art have viewed oral administration of therapeutic agents as ineffective and unpredictable. It is respectfully submitted that Jamas's unsubstantiated, unexemplified and nonenabling disclosure of oral administration of a glucan is cannot be sufficient to remedy the unpredictability in the art.

From the clinical perspective, oral administration of β-glucan, or any therapeutic agent, provides several clinically important benefits. Oral administration is non-invasive as compared to intravenous, subcutaneous, intramuscular or intraperitoneal routes. Therefore, orally administering β-glucans provides a more convenient, less painful and less expensive method for delivering therapeutic agents. This results in greater patient compliance with treatment regimens, and thus, more effective treatment. It is respectfully submitted that the same benefits would result from

orally administering β-glucans to enhance the effects of anti-tumor antibodies. See Exhibit E, p. 142, col. 2, 2nd para., stating:

Any company to develop such a system would almost certainly supplant the current injection-based industry. Thus, there is great interest in developing a method of oral [protein] delivery.

In sum, Applicant's treatment regimen satisfies a long-felt and continuing need in the art for orally administered β-glucans to more conveniently enhance anti-cancer antibodies. Accordingly, it is respectfully submitted that the rejection under § 103(a) based on the combination of Yan in view of Jamas should be withdrawn.

7. The Unpredictability of Administering Macromolecules Orally is Based on Several Factors

Examiner's attention is respectfully directed to Exhibit E, pp. 143-144, and Exhbibit F , p.5, col. 1. In general, the articles compare different routes of drug administration.

With respect to administering any therapeutic agent via the oral route consideration must be given to the significant barriers that may impede or prevent the agent from reaching the bloodstream for systemic distribution throughout the body. Therefore, most therapeutic agents are designed to possess the ability to traverse epithelial layers by diffusing across the lipophilic plasma membrane of the intestinal epithelial cells.

This route was not considered effective for glucans due to their physical properties. For example, glucans have a broad spectrum of molecular weights that encompasses high molecular weights, e.g., the macromolecular range. In addition, glucans possess a high

content of polar hydroxyl groups, which altogether, impart properties that would not be expected to result in an efficient diffusion into and across the intestinal mucosa. Exhibit F, page 3, col. 2, last para.

Persons of ordinary skill in the art would not have expected glucan molecules to traverse the intestinal mucosa, either by passing between "leaky" epithelial cells (the paracellular route) or by transcellular routes including diffusion across the layer or by receptor-mediated transcytosis. Exhibit E, p. 143, col. 2, to 144, col. 1, last para.; Exhibit F, p. 3, col. 2. Intravenously administered agents, including glucans are not expected to encounter these barriers but would be expected to be distributed more efficiently.

In conclusion, persons of ordinary skill in the art would not have preferred the oral route over parenteral routes. This is largely based on the physiological factors resulting in erratic, i.e., unpredictable, bioavailability of orally administered agents. Therefore, persons of ordinary skill in the art could not have had a reasonable expectation of success in achieving the claimed subject matter.

In view of the knowledge of persons of ordinary skill in the art, it is suggested that the ordinary skill artisan could not have viewed Jamas's reference to orally administering glucans as providing a reasonable expectation of success. It is noted that the article in Exhibit E was published six years after Jamas. Therefore, it is respectfully submitted that there was no reasonable expectation of success in modifying Yan according to Jamas.

Withdrawal of the rejection under § 103(a) is respectfully requested.

8. Jamas's Disclosure of Oral Administration of Glucan Amounts to an "Obvious to Try" Invitation to Experiment

An applicant may argue that an examiner is applying an improper "obvious to try" rationale in support of an obviousness rejection. MPEP 2145.

"The admonition that 'obvious to try' is not the standard under § 103 has been directed mainly at two kinds of error. One kind of error in which an 'obvious to try' rationale is improper is where a reference merely suggests to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. MPEP 2145. (Emphasis added). It is respectfully submitted that the pre-filing date literature, like Jama's reference, does not provide any guidance to orally administering glucans so as to enhance the anti-tumor effects of an administered antibody.

In In re O'Farrell, (7 USPQ2d 1673, 1681 (Fed. Cir. 1988)) the court held that properly relying on a prior art requires that the reference contain a (1) detailed enabling methodology, (2) a suggestion to modify the prior art to produce the claimed invention, and (3) evidence suggesting the modification would be successful. It is respectfully submitted that requirements (1) and (3) are nowhere to be found in the prior art of record. Further, requirement (2) may be generally provided by the desirability to find additional methods to treat tumors. However, this general

level of suggestion is insufficient to satisfy the specific suggestion required by (2).

In conclusion, it is respectfully suggested that neither Jamas nor Yan, individually or in combination, disclose any detailed methodology enabling the oral administration of β-glucan in a combination therapy. It is further believed in good faith that no such details or methodology existed prior to Applicant's priority date.

In accordance with the cited case law and MPEP 2145, it is respectfully suggested that the rejection under § 103(a) be withdrawn.

9. Secondary References

The foregoing remarks are believed sufficient to overcome the rejections under § 103(a). Therefore, it is respectfully submitted that a discussion of the secondary references, Cheever, Onizuka, Herrera, Rai, or Yue, is not necessary. These references merely recite antigens and do not address the documented insufficiencies in Yan and Jamas. Nor do they provide any evidence or guidance to reasonably determine that Examiner's proposed modification of Yan would be successful.

In view of this analysis, Applicant respectfully suggests that the Office Action does not reach the level of a prima facie case of obviousness. Accordingly, withdrawal of the rejection is respectfully requested.

It respectfully suggested that the foregoing claim amendments and remarks traverse all double patenting rejections and issues that

have been raised under §103(a) and §112,1st paragraph. Therefore, allowance of all claims is respectfully requested.

CONCLUSION

In conclusion, the evidence cited clearly supports that one of ordinary skill in the art would not have been motivated to modify Yan's method by using an oral route as suggested by Jamas et al. The work cited and described in Exhibits A and B, indicate that prior to Applicant's work, the outcome of oral administration of glucan was unpredictable, and usually, showed a lack of effect.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below. If any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

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